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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,744

09/19/2005

Alfred Westfechtel

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2000 MARKET STREET  
PHILADELPHIA, PA 19103

EXAMINER

CLARK, SARA ELIZABETH

ART UNIT

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4121

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,744	<b>Applicant(s)</b> WESTFECHTEL ET AL.	
	<b>Examiner</b> SARA E. CLARK	<b>Art Unit</b> 4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/19/2005</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

### **NON-FINAL REJECTION**

This application is a national stage application of PCT/EP04/02440, filed 3/10/2004, which claims benefit of priority to German application no. 103 12 000.9, filed 3/19/2003. Claims 12-36, as amended, are pending.

#### ***Priority***

1. Applicant's claim to foreign priority is acknowledged. A review of the related applications indicates that the claims of the instant application are supported in the disclosures of the parent applications. Therefore, Applicant is entitled to an effective filing date of 3/10/2004 and a foreign priority date of 3/19/2003.

#### ***Information Disclosure Statement***

2. All references submitted by Applicant on the IDS dated 9/19/2005 have been considered.

#### ***Objections***

3. Dependent claims 32-36 are objected to on the grounds that they are drawn to a product (an emulsifier or co-emulsifier) but depend from independent claim 21, which is drawn to a process. However, this appears to be a typographical error, such that claims 32-36 were intended to depend from claim 31. Therefore, the examiner has interpreted "according to claim 21" recited by claims 32-36 as "according to claim 31," which is

drawn to the same product as claims 32-36 (an emulsifier or co-emulsifier). If this was Applicant's intent, appropriate correction is required.

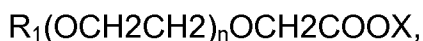
***Claim Rejections - §103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 12-14, 16-19, 21-25, 27-29, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milstein et al. (US Pat. 6,394,230, issued 5/28/2002) and Behler et al. (DE Pat. 19740954, published 12/24/1998, provided by Applicant on the IDS dated 9/19/2005), in view of Patrick et al. (EP 0897 671 B1, published 2/24/1999, provided by Applicant on the IDS dated 9/19/2005) and Ishii et al. (US Pat. 6,447,790, issued 9/10/2002).

Milstein et al. teach sterol and stanol esters made by reacting phytosterol or phytostanols, preferably  $\beta$ -sitosterol, with a carboxylic acid having from 6 to 22 carbon atoms in the presence of an esterification catalyst (col. 2, lines 27-47), noting that any aliphatic, cycloaliphatic, or aromatic mono- or poly-carboxylic acid having at least two carbon atoms, and mixtures thereof, is suitable (col. 5, lines 3-8). Fitting this description, Behler et al. (p. 2 of English translation) teaches ether carboxylic acids of the formula



- where  $R_1$  is a  $C_{6-22}$  carbon alkyl, alkenyl, and/or alkylphenyl;
- $n = 1-10$ ; and
- $X$  is a hydrogen or an alkali metal.

This compound reads on the ether carboxylic acid component of instant claim 12, which recites the formula



- where  $R$  is a  $C_{1-50}$  alkyl, alkenyl, and/or alkylphenyl;
- $OAlk$  can be a ring-opened ethylene, propylene, or butylene oxide (e.g.,  $OCH_2CH_2$ ), and
- $n = 1-100$ .

While the compounds of Milstein are used as food additives to lower blood serum cholesterol levels, Behler et al. teach the use of these ether carboxylic acids as anionic surfactants. The rationale to prepare a sterol or stanol ester of an ether carboxylic acid to yield the claimed compounds is found in Patrick et al., noting that phytosterols and phytostanols are immiscible in water and have poor solubility in lipids (p. 2, line 20). Thus, either a surfactant or emulsifier must be added to the composition for effective dispersal and absorption; or the surfactant or emulsifier can be omitted if the sterols have been esterified with a highly hydrophilic compound, such as citric acid or tartaric acid, i.e., carboxylic acids, which would preclude the need for a separate emulsifier (p. 4, lines 17-19). Ether carboxylic acids have been noted as suitable anionic surfactants

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for this purpose in other body treating compositions containing sterol and/or stanol esters (see, e.g., Ishii et al., col. 8, lines 22-35).

The motivation to reduce complexity, costs, and inefficiency by combining two functions into one component is inherent in any technical endeavor; and while the specification notes that the instant compounds are self-emulsifying, they are preferably used in combination with an additional emulsifier or surfactant in any case (page 10, line 10), which is known in the art. Therefore, claim 12, drawn to sterol and stanol esters; claim 21, drawn to a method of preparing those compounds; claim 28, drawn to these compounds for use as a food or food supplement; and claim 31, drawn to these compounds for use as an emulsifier or co-emulsifier, is obvious over Milstein et al. in combination with Behler et al.

The compounds of Behler et al. also read on claims 13, 22, and 32, which limit R to a linear C<sub>1-36</sub> alkyl group; claim 14, which limits R to a linear C<sub>1-18</sub> alkyl group; claims 16, 23, and 33, which limit OAlk to OCH<sub>2</sub>CH<sub>2</sub>; and claims 17, 24, and 34, which limit n to a number from 1-20. In combination with Behler et al., Milstein et al. reads on claims 18, 25, 29, and 35, which limit sterols and stanols to phytosterols and phytostanols (col. 1, lines 18-28); claim 19, which limits phytosterols and phytostanols to  $\beta$ -sitosterol, campesterol, stigmasterol, brassicasterol, and/or campestanol (col. 2, lines 40-47, noting the suitability of Generol 122N, as does the instant specification at page 5); and claims 28-30, which recite the use of phytosterol and phytostanol esters as food or food supplements (cols. 9-10).

Milstein et al., Behler et al., and Patrick et al. teach the use of phytosterol and/or phytostanol esters as food supplements or additives, but not for use in cosmetic compositions. However, Ishii et al. teach the use of phytosterol and phytostanol esters of N-long chain acyl neutral amino acids in cosmetic compositions (col. 6, line 54 to col. 7, line 24); and that ether carboxylic acids are suitable surfactants for use with these phytosterol and phytostanol esters (col. 8, lines 22-35). Therefore, including an ether carboxylic acid with a phytosterol or phytostanol ester in a cosmetic composition, as recited by claim 27, either as separate components or as one bifunctional compound, would have been obvious over Ishii et al.

Taken together, the compounds, functions, and uses of the claimed invention were known, such that combining them would have been obvious to a person of ordinary skill in the art at the time the invention was made.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Milstein et al., Behler et al., and Patrick et al., as applied to claims 12-14, 16-19, 21-25, 27-29, and 31-35 above, and further in view of Noh et al. (WO 2000/52029, published 9/8/2000, provided by Applicant on the IDS dated 9/19/2005).

The ether carboxylic acids of Behler et al. include C<sub>2-36</sub> alkyl groups without a terminal hydroxyl group. However, Noh et al. teach ether dicarboxylic acids esterified to a phytosterol at one terminus and a C<sub>2</sub> alkyl with a terminal hydroxyl group at the other terminus (p. 7, lines 18-23). The terminal hydroxyl group of Noh et al. is derived from a ring-opened epoxide rather than a difunctional alcohol, but claim 15 is drawn to the compound, not the method of making it. However one arrives at the final compound,

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adding a hydroxyl group to one terminus of the compounds of Behler et al. would have been obvious over Noh et al. The purpose of esterifying a sterol with a long-chain ether carboxylic acid is to confer a self-emulsifying or surfactant property to the sterol; i.e., to increase its miscibility in both oil and water. The hydrocarbon component would be predicted to accomplish this in hydrophobic phases, while the additional terminal hydroxyl group would be predicted to boost solubility in aqueous environments. Thus, including a terminal hydroxyl group as recited by the definition of R in claim 15 would have been an obvious modification to the ether carboxylic acids of Behler et al. at the time the invention was made.

7. Claims 20, 26, 30, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milstein et al., Behler et al., and Patrick et al., as applied to claims 12-14, 16-19, 21-25, 27-29, and 31-35 above, and further in view of Piironen et al. (J. Food Comp. Anal. 13, 619-24, 2000).

Patrick et al. teach that  $\beta$ -sitosterol is known to be the most effective plant sterol for lowering blood serum cholesterol (p. 2, line 58), and that preferred sources of phytosterols include rapeseed oil (p. 4, line 57). Piironen et al. teach that rapeseed oil is the richest source of plant sterols (figure 2, p. 621), such that limiting the source of phytosterols or phytostanols to rapeseed oil, as recited by claims 20, 26, 30, and 36, would have been obvious to one skilled in the art at the time the invention was made.

### ***Conclusion***

8. Claims 12-36 are rejected.

9. Any inquiry concerning this communication or earlier communications from the



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examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Monday - Thursday, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sec

/Patrick J. Nolan/  
Supervisory Patent Examiner, Art Unit 4121